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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/616,438 | 07/09/2003 | Samuel D. Prien | | 9166 |

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| EXAMINER | |
|---|---|
| DOERRLER, WILLIAM CHARLES | |
| **ART UNIT** | **PAPER NUMBER** |
| 3744 | |

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/616,438 | PRIEN ET AL. | |
| | Examiner | Art Unit | |
| | William C Doerrler | 3744 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *40-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by le Roux Murray (4,888,956).

Le Roux Murray discloses a cooling system for biological substances (col. 1 line 19) which circulates a cooling fluid in a continuously constant and repeatable pattern (col. 6 line 17) and at a fixed uniform temperature (col. 6 lines 18-19). The viabilities of claims 47-49 are seen as inherent to the structure claimed and shown by le Roux Murray since applicant has not claimed any steps or structure which are not shown by the reference.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-45 and 50-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of le Roux Murray.

Schwartz discloses applicants' basic inventive concept, a cooling system for biological samples which circulates a coolant which is maintained at a constant temperature (column 9 line 42) by an external cooling system 33, substantially as claimed with the exception of maintaining a constant velocity for the coolant and using an impeller located in the coolant. Le Roux Murray shows this feature to be old in the sample cooling art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of le Roux Murray to modify the sample cooler of Schwartz by circulating the coolant at a constant velocity to promote even cooling and to place the impeller in the coolant to conserve space. In column 10 line 12, Schwartz teaches that samples may be cooled to -22 C, within applicants' claimed range of claims 44 and 51. The claimed viability levels after thawing are seen as inherent since the combination of references teaches applicants' cooling steps and structure. In regard to claims 45,51 and 57, the size and capacity of the system is seen as a matter of design choice for an ordinary practitioner in the art which will depend on the number of samples desired to treated.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,615,592. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are identical with the exception of the removal of the vitrification of the samples. The current claims will dominate the earlier claims since it is impossible to perform the earlier patented claims without performing the current claims. It is considered obvious to an ordinary practitioner in the art that the earlier patented claims could be performed without vitrification to merely provide rapid cooling of biological samples.

Claims 40-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/319,454 as presented as US2003/0154729) in view of Schwartz. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are identical with the exception of the removal of

the vitrification of the samples. The current claims will dominate the earlier claims since it is impossible to perform the earlier patented claims without performing the current claims. It is considered obvious to an ordinary practitioner in the art that the earlier filed claims could be performed without vitrification to merely provide rapid cooling of biological samples. It appears that new claims have been filed in the '454 application, but these two render the current claims obvious. The current claims differ from the pending claims of the '454 application only in the addition of a constant temperature for the coolant. Schwartz shows this feature to be old in the biological sample cooling art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Schwartz to modify the cooler of the earlier filed application by maintaining a constant temperature for the coolant to ensure high quality freezing to maintain viability of the samples.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 37 of U.S. Patent No. 6,519,954. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are identical with the exception of the removal of the vitrification of the samples. The current claims will dominate the earlier claims since it is impossible to perform the earlier patented claims without performing the current claims. It is considered obvious to an ordinary practitioner in the

art that the earlier patented claims could be performed without vitrification to merely provide rapid cooling of biological samples.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Swenson et al shows a system for maintaining viability of biological samples by circulating a coolant. Zurek et al shows a system for treating biological samples with a constant velocity cooling fluid stream.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William C Doerrler whose telephone number is (703) 308-0696. The examiner can normally be reached on Monday-Friday 6:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise Esquivel can be reached on (703) 308-2597. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William C Doerrler
Primary Examiner
Art Unit 3744

WCD